

## **§ 225.120**

reports of clinical and other experience with the drug shall be maintained and reported, under § 510.301 of this chapter.

[41 FR 52618, Nov. 30, 1976, as amended at 51 FR 7390, Mar. 3, 1986; 57 FR 6475, Feb. 25, 1992; 64 FR 63203, Nov. 19, 1999]

## **Subpart F—Facilities and Equipment**

SOURCE: 51 FR 7390, Mar. 3, 1986, unless otherwise noted.

### **§ 225.120 Buildings and grounds.**

Buildings used for production of medicated feed shall provide adequate space for equipment, processing, and orderly receipt and storage of medicated feed. Areas shall include access for routine maintenance and cleaning of equipment. Buildings and grounds shall be constructed and maintained in a manner to minimize vermin and pest infestation.

### **§ 225.130 Equipment.**

Equipment shall be capable of producing a medicated feed of intended potency and purity, and shall be maintained in a reasonably clean and orderly manner. Scales and liquid metering devices shall be accurate and of suitable size, design, construction, precision, and accuracy for their intended purposes. All equipment shall be designed, constructed, installed, and maintained so as to facilitate inspection and use of cleanout procedure(s).

### **§ 225.135 Work and storage areas.**

Work areas and equipment used for the production or storage of medicated feeds or components thereof shall not be used for, and shall be physically separated from, work areas and equipment used for the manufacture and storage of fertilizers, herbicides, insecticides, fungicides, rodenticides, and other pesticides unless such articles are approved or index listed for use in the manufacture of animal feed.

[72 FR 69120, Dec. 6, 2007]

## **21 CFR Ch. I (4–1–12 Edition)**

## **Subpart G—Product Quality Assurance**

SOURCE: 51 FR 7390, Mar. 3, 1986, unless otherwise noted.

### **§ 225.142 Components.**

Adequate procedures shall be established and maintained for the identification, storage, and inventory control (receipt and use) of all Type A medicated articles and Type B medicated feeds intended for use in the manufacture of medicated feeds to aid in assuring the identity, strength, quality, and purity of these drug sources. Packaged Type A medicated articles and Type B medicated feeds shall be stored in designated areas in their original closed containers. Bulk Type A medicated articles and bulk Type B medicated feeds shall be identified and stored in a manner such that their identity, strength, quality, and purity will be maintained. All Type A medicated articles and Type B medicated feeds shall be used in accordance with their labeled mixing directions.

### **§ 225.158 Laboratory assays.**

Where the results of laboratory assays of drug components, including assays by State feed control officials, indicate that the medicated feed is not in accord with the permissible limits specified in this chapter, investigation and corrective action shall be implemented immediately by the firm and such records shall be maintained on the premises for a period of 1 year.

### **§ 225.165 Equipment cleanout procedures.**

Adequate procedures shall be established and used for all equipment used in the production and distribution of medicated feeds to avoid unsafe contamination of medicated and nonmedicated feeds.

## **Subpart H—Labeling**

### **§ 225.180 Labeling.**

Labels shall be received, handled, and stored in a manner that prevents label mixups and assures that the correct labels are used for the medicated feed. All deliveries of medicated feeds,

whether bagged or in bulk, shall be adequately labeled to assure that the feed can be properly used.

[51 FR 7390, Mar. 3, 1986]

### Subpart I—Records

#### § 225.202 Formula, production, and distribution records.

Records shall be maintained identifying the formulation, date of mixing, and if not for own use, date of shipment. The records shall be adequate to facilitate the recall of specific batches of medicated feed that have been distributed. Such records shall be retained on the premises for 1 year following the date of last distribution.

(Approved by the Office of Management and Budget under control number 0910-0152)

[51 FR 7390, Mar. 3, 1986]

## PART 226—CURRENT GOOD MANUFACTURING PRACTICE FOR TYPE A MEDICATED ARTICLES

### Subpart A—General Provisions

Sec.

226.1 Current good manufacturing practice.  
226.10 Personnel.

### Subpart B—Construction and Maintenance of Facilities and Equipment

226.20 Buildings.  
226.30 Equipment.

### Subpart C—Product Quality Control

226.40 Production and control procedures.  
226.42 Components.  
226.58 Laboratory controls.

### Subpart D—Packaging and Labeling

226.80 Packaging and labeling.

### Subpart E—Records and Reports

226.102 Master-formula and batch-production records.  
226.110 Distribution records.  
226.115 Complaint files.

AUTHORITY: 21 U.S.C. 351, 352, 360b, 371, 374.

SOURCE: 40 FR 14031, Mar. 27, 1975, unless otherwise noted.

### Subpart A—General Provisions

#### § 226.1 Current good manufacturing practice.

(a) The criteria in §§ 226.10 through 226.115, inclusive, shall apply in determining whether the methods used in, or the facilities and controls used for the manufacture, processing, packing, or holding of a Type A medicated article(s) conform to or are operated or administered in conformity with current good manufacturing practice to assure that a Type A medicated article(s) meets the requirements of the act as to safety, and has the identity and strength, and meets the quality and purity characteristics which it purports or is represented to possess, as required by section 501(a)(2)(B) of the act. The regulations in this part 226 permit the use of precision, automatic, mechanical, or electronic equipment in the production of a Type A medicated article(s) when adequate inspection and checking procedures or other quality control procedures are used to assure proper performance.

(b) In addition to maintaining records and reports required in this part, Type A medicated articles requiring approved NADAs are subject to the requirements of § 514.80 of this chapter. Similarly, Type A medicated articles listed in the index are subject to the requirements of § 516.165 of this chapter.

[40 FR 14031, Mar. 27, 1975, as amended at 68 FR 15364, Mar. 31, 2003; 72 FR 69120, Dec. 6, 2007]

#### § 226.10 Personnel.

The key personnel and any consultants involved in the manufacture and control of the Type A medicated article(s) shall have a background of appropriate education or appropriate experience or combination thereof for assuming responsibility to assure that the Type A medicated article(s) has the proper labeling and the safety, identity, strength, quality, and purity that it purports to possess.